

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 01D-0519]

Medical Devices; Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry." This document encourages manufacturers of approved conventional cardiac ablation catheters to submit supplements to broaden their labeling from arrhythmia-specific indications to a generic arrhythmic treatment indication. The Center for Devices and Radiological Health (CDRH) is issuing this guidance document to allow companies to label these products for a broader indication without submitting additional clinical information. This recommendation is based on a comprehensive search of the medical literature.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Lesley L. Ewing, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320.

SUPPLEMENTARY INFORMATION:

I. Background

This final guidance entitled "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry" recommends that manufacturers of approved conventional cardiac radiofrequency ablation catheters submit a premarket approval supplement to obtain a generic indication for creating endocardial lesions to treat arrhythmias. The guidance document provides evidence from the medical literature to support this broadening of indications from arrhythmia-specific indications to a generic arrhythmia treating indication.

The guidance was made available as a draft for comment on December 7, 2001 (66 FR 63546). The comment period closed March 7, 2002. FDA received two comments, both agreeing with FDA's recommendation. One of these comments also asked that FDA expand the definition of conventional cardiac catheter. FDA disagrees and is issuing the guidance with no changes.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on generic indications for cardiac ablation catheters. It does not create or confer any rights for or on any person and does

not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

III. Electronic Access

In order to receive the guidance entitled "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1382) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

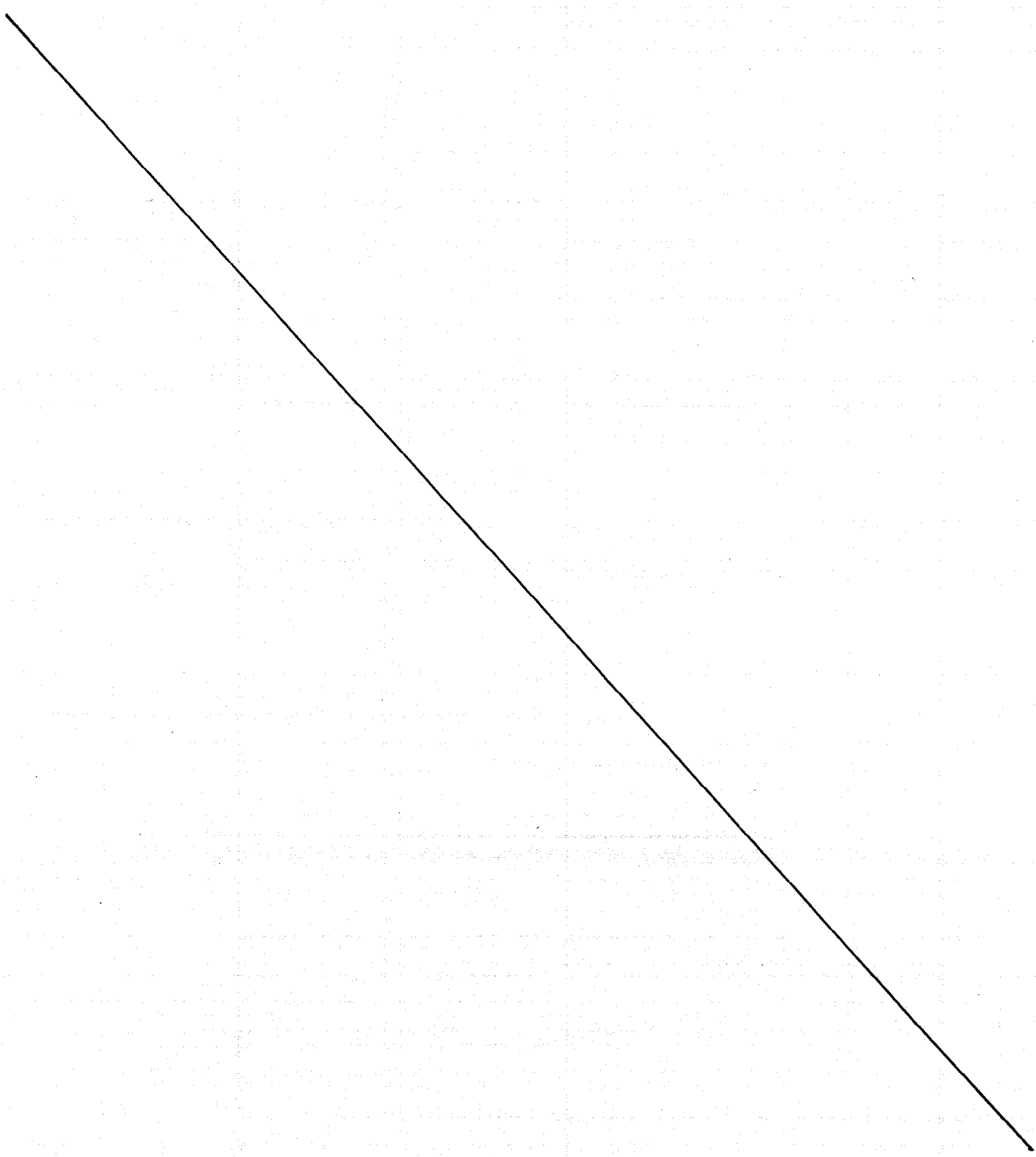
Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in the section on Generic Arrhythmia Indications in the guidance was approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with



the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/21/02
June 21, 2002.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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